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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,846	01/16/2004	Tianhua Hu	HYS-46CIP	7344

34285 7590 10/04/2006

NUVELO, INC
201 INDUSTRIAL ROAD
SUITE 310
SAN CARLOS, CA 94070

EXAMINER

MEAH, MOHAMMAD Y

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/758,846

Applicant(s)

HU ET AL.

Examiner

Mohammad Meah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-11, 20 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-11, 20, 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

With preliminary amendment of this application, the applicant, on date 07/13/2006 elected without traverse Group 38(named wrongfully group II by applicant) , claims 9-11 and 20, 22, SEQ ID NO: 32) for examination.

Election/Restriction

During preliminary amendment of this application, the applicant, on date 07/13/2006 elected without traverse Group 38 (claims 9-11 and 20, 22), drawn to isolated protein comprising the amino acid sequence of SEQ ID NO: 32 for examination. Groups 1- 37 and 39-135 (claims 1-8, 12-19 and 21) of election/restriction-office action of date 09/23/05 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Groups.

Priority

Acknowledgement is made of applicant's priority date based on CIP 10/005,499 ABN filed 12/03/2001, pct/US O2/38526 ABN, filing date of 12/2/2002.

Claim Rejections

35 U.S.C 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 9-11 and 20, 22 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The specification fails to teach a specific and substantial utility for the protein set forth by SEQ ID NO: 32. Based on the title of the instant invention and the specification at page 15-17, the asserted utility for said protein is as C1q domain protein. The family of C1q is a large and variable family of proteins with a large number of variable substrates and the potentiality of being involved in many different cellular processes and diseases (Background section of the specification). The specification fails to show a working example of a specific utility for the putative C1q domain of SEQ ID NO: 32. Neither specific substrates that can be cleaved by said putative C1q domain of SEQ ID NO: 32, specific biological processes mediated by said putative C1q domain of SEQ ID NO: 32, specific diseases due to dysfunction of said putative C1q domain of SEQ ID NO: 32, nor pathological conditions that can

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be treated with said putative C1q domain of SEQ ID NO: 32, are disclosed nor shown by any working examples.

As such a skilled artisan would not find an assertion that the protein of SEQ ID NO:32 is a Cq1 protein specific and substantial without further supporting evidence. No such evidence is presented in the specification (such as C1Q activity supported by an assay).

Claims 9-11, 20 and 22 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with utility requirement of U.S.C. 101.

CLAIM Rejection - 35 U.S.C 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 9-11 and 20, 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Tang et al. (WO 03/025148). Tang et al. teach polypeptide of SEQ ID NO: 509, composition, kit comprising said polypeptide and polypeptide array (claims 11, 21 and page 201) which is 100% identical to the SEQ ID NO: 32 of the instant application.

Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees.

See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164

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USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9, 10, 11, 20 and 22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10, 9, 11 and 20, 22 of copending Application No.10496905. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759

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F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 10 and 9 of instant application comprises a polypeptide of SEQ ID NO: 32 or encoded by DNA of SEQ ID NO: 31 and claims 10 and 9 of copending application 10496905 comprises a polypeptide of SEQ ID NO: 302 which is 100% identical to SEQ ID NO: 32 of the instant application and encoded by DNA of o SEQ ID NO: 301 which is 100% identical to DNA of SEQ ID NO: 31 of the instant application. The remaining claims 11, 20 and 22 of instant application (composition, ki and polypeptide array) ,dependent claims of 10 or 9 of instant application, are identical to those of claims 11, 20 and 22 (composition, ki and polypeptide array), dependent claims of 10496905 thereof. As such the claims of the instant application and those of the copending application differ only in the scope of polypeptide. Therefore, claims 9, 10, 11, 20 and 22 herein are anticipated by claims 10, 9, 11 and 20, 22 of copending Application No.10496905

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax

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phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Mohammad Younus Meah, PhD

Examiner, Art Unit 1652

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